

# Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy, and surgical stripping for great saphenous varicose veins with 3-year follow-up

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**Introduction:** This study compares the outcome 3 years after treatment of varicose veins by endovenous laser ablation (EVLA), radiofrequency ablation, ultrasound-guided foam sclerotherapy (UGFS), or surgery by assessing recurrence, Venous Clinical Severity Score (VCSS), and quality of life (QOL).

**Methods:** A total of 500 patients (580 legs) were randomized to one of the three endovenous treatments or high ligation and stripping of the great saphenous vein (GSV). Follow-up included clinical and duplex ultrasound examinations and VCSS and QOL questionnaires. Kaplan-Meier (KM) life-table analysis was used. *P* values below .05 were considered statistically significant.

**Results:** At 3 years, eight (KM estimate, 7%), eight (KM estimate, 6.8%), 31 (KM estimate, 26.4%), and eight (KM estimate, 6.5%) of GSVs recanalized or had a failed stripping procedure (more than 10 cm open refluxing part of the

treated GSV; CLF, EVLA, UGFS, and stripping, respectively; *P* < .01). Seventeen (KM estimate, 14.9%), 24 (KM estimate, 20%), 20 (KM estimate, 19.1%), and 22 (KM estimate, 20.2%) legs developed recurrent varicose veins (*P* = NS). The patterns of reflux and location of recurrent varicose veins were not different between the groups. Within 3 years after treatment, 12 (KM estimate, 11.1%), 14 (KM estimate, 12.5%), 37 (KM estimate, 31.6%), and 18 (KM estimate, 15.5%) legs were retreated in the CLF, EVLA, UGFS, and stripping groups, respectively (*P* < .01). VCSS, SF-36, and Aberdeen QOL scores improved significantly in all the groups with no difference between the groups.

**Conclusions:** All treatment modalities were efficacious and resulted in a similar improvement in VCSS and QOL.

However, more recanalization and reoperations were seen after UGFS. (*J Vasc Surg: Venous and Lym Dis* 2013;■:1-8.)

Varicose veins are common and affect approximately 25% of Western adults.<sup>1</sup> The condition is most often associated with great saphenous vein (GSV) reflux. Until recently, the gold standard treatment of such condition has been high ligation combined with stripping and phlebectomies. Such treatment efficiently improves symptoms and quality of life (QOL).<sup>2,3</sup> However, the rate of recurrence, which may be caused by neovascularization, progression of disease, or technical or tactical errors, is high.<sup>4-7</sup>

In the recent decade, minimally invasive treatments, based on radiofrequency ablation (RFA) or endovenous laser ablation (EVLA) of the saphenous veins (thermoablation) has more or less replaced surgical stripping in the U.S., whereas in Europe, stripping is still the most used treatment. In addition, ultrasound-guided foam sclerotherapy (UGFS) has become increasingly popular.

Indeed, in the American guidelines for treatment of venous disease, thermoablation is preferred instead of surgical stripping.<sup>8</sup> According to the guidelines, such preference is based on the patient's recovery, which, in some studies, appears to be easier following endovenous treatment. In addition, several studies have described a high degree of efficacy regarding endovenous ablation of the GSV in the short and medium term.<sup>9</sup> However, little is known regarding the difference in clinical recurrence between the endovenous methods and surgery.<sup>10</sup> The present randomized trial, which compares RFA, EVLA, UGFS, and stripping, was initiated in 2007. The short-term results (1-year) were published in 2011.<sup>11</sup> The present publication report the medium-term (3-year) outcome and describes the clinical and ultrasound recurrence, number of reoperations, Venous Clinical Severity Score (VCSS), and QOL. The regional ethics committee approved the study. All patients gave informed consent.

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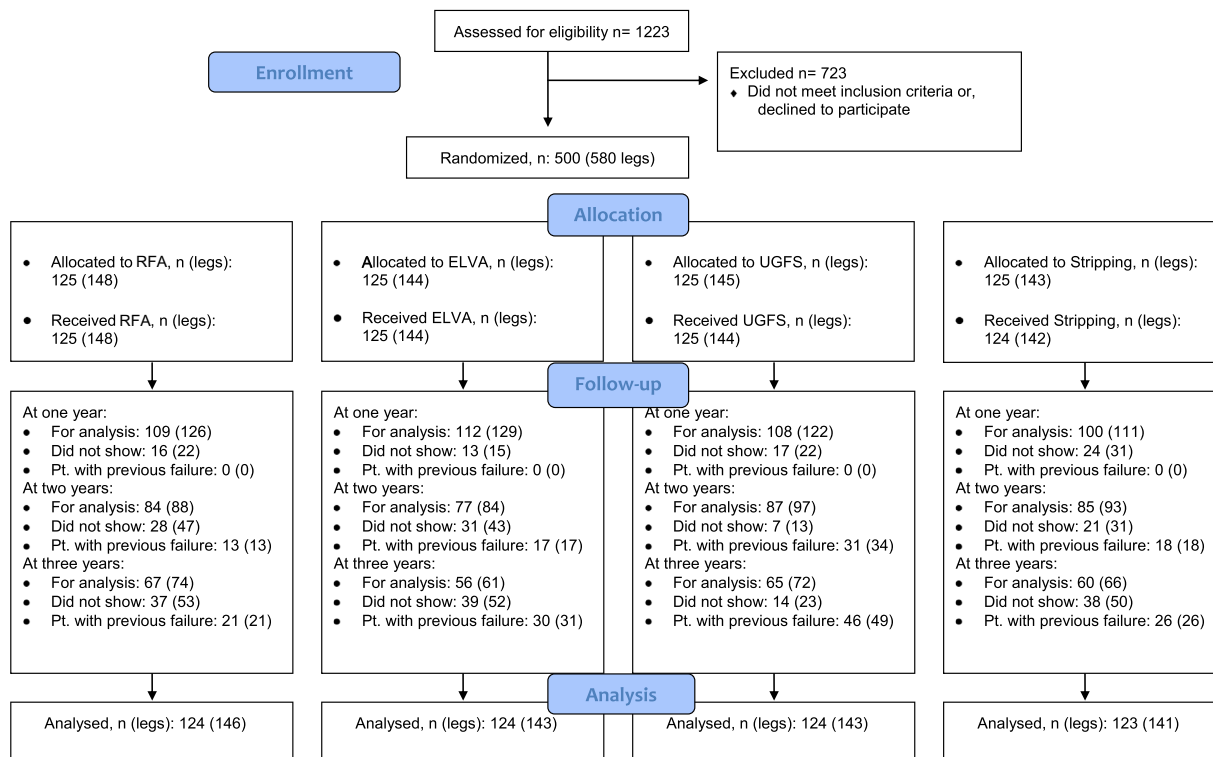
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## METHODS

The study was conducted in two private surgical centers, which work under contract to the national health care insurance in Denmark. The primary endpoint was closed or absent GSV. An open refluxing segment of the treated part of the GSV of 10 cm or more was



**Fig 1.** CONSORT flow chart. *EVLA*, Endovenous laser ablation; *RFA*, radiofrequency ablation; *UGFS*, ultrasound-guided foam sclerotherapy.

considered a failure to strip the vein (technical failure) or recanalization. Secondary endpoints were the presence of varicose veins during follow-up, frequency of reoperations, VCSS, and QOL. The details of the methodology have been previously described.<sup>11</sup> In brief, consecutive patients with symptomatic varicose veins and GSV incompetence, CEAP C<sub>2-4</sub>E<sub>p</sub>A<sub>s</sub>P<sub>r</sub>, were randomized to the trial using sealed envelopes. Exclusion criteria were duplication of the saphenous trunk or an incompetent accessory GSV (AAGSV), small saphenous or deep venous incompetence, previous deep vein thrombosis, arterial insufficiency, or a tortuous GSV rendering the vein unsuitable for endovenous treatment. All treatments and assessments were performed by one of three vascular and general surgeons with experience in the management of venous disease. Bilateral treatment was permitted, provided both limbs received the same treatment during the same operation. Patients who had undergone previous high ligation or phlebectomies were included in the trial. The patients were treated with one of the following methods: RFA (ClosureFast [CLF]; Covidien, Mansfield, Mass), EVLA (ELVES, Ceralas D 980 or D 1470, bare fiber; Biolitec, Bonn, Germany), UGFS with Aethoxysclerol 3%, 2-mL solution mixed with 8-mL air according to the method of Tessari (Polidocanol; Kreussler, Wiesbaden, Germany), or PIN stripping. All treatments were performed in a treatment room under tumescent local anesthesia using

**Table I.** Baseline characteristics in patients treated for varicose veins and GSV incompetence

|  | <i>RFA</i> | <i>EVLA</i> | <i>UGFS</i> | <i>Stripping</i> |
|--|------------|-------------|-------------|------------------|
| No. of patients                                  | 125        | 125         | 125         | 124              |
| No. of legs                                      | 148        | 144         | 144         | 142              |
| Bilateral <sup>a</sup>                           | 23         | 19          | 19          | 18               |
| Age, years <sup>b</sup>                          | 51 (23-77) | 52 (18-74)  | 51 (18-75)  | 50 (19-72)       |
| Female <sup>c</sup>                              | 70         | 72          | 76          | 77               |
| CEAP C <sub>2</sub> -C <sub>3</sub> <sup>a</sup> | 92         | 95          | 96          | 97               |
| CEAP C <sub>4</sub> -C <sub>6</sub> <sup>a</sup> | 8          | 5           | 4           | 3                |

*EVLA*, Endovenous laser ablation; *GSV*, great saphenous vein; *RFA*, radiofrequency ablation; *UGFS*, ultrasound-guided foam sclerotherapy.

<sup>a</sup>% of legs.

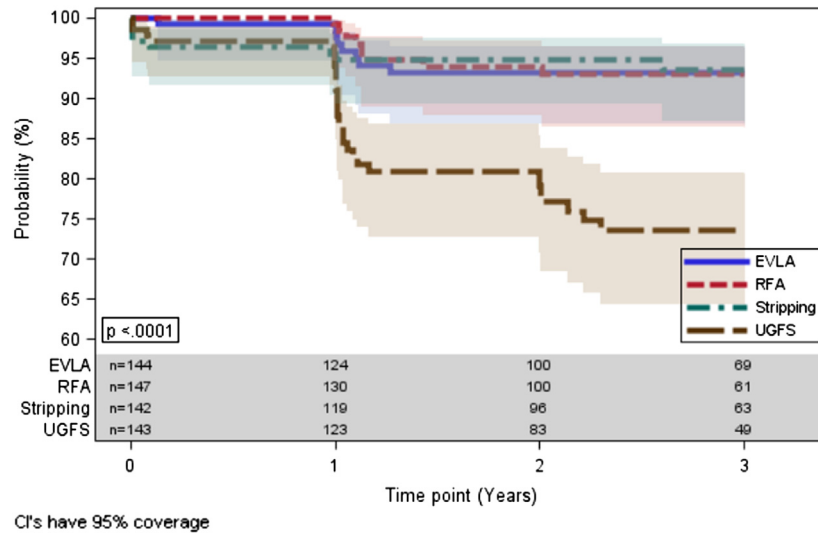
<sup>b</sup>Mean (range).

<sup>c</sup>% of patients.

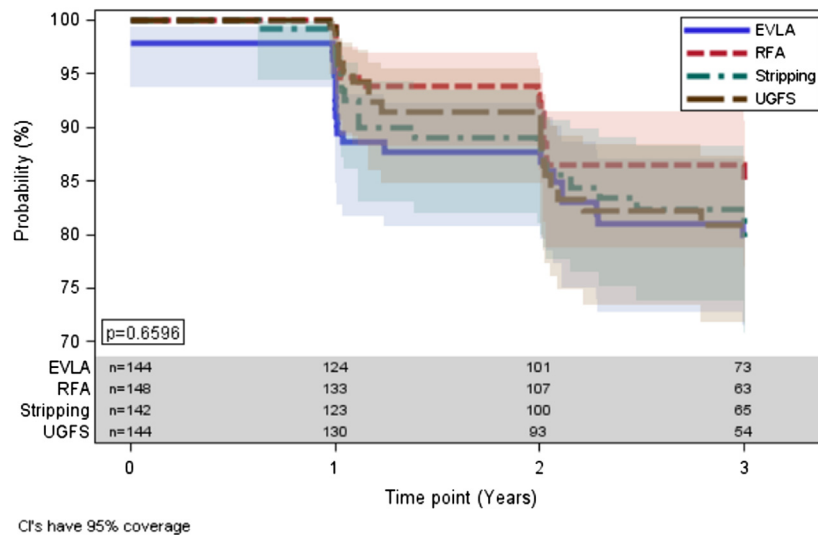
a solution of 0.1% lidocaine with adrenaline and bicarbonate. A light sedation with midazolam and alfentanil or diazepam was administered intravenously in most cases.

The surgical procedure was carried out through a 4- to 6-cm incision in the groin, with flush division and ligation of the GSV and division and ligation of all tributaries. The GSV was then removed to just below the knee using a pin stripper.

The CLF procedure was performed according to the manufacturer's recommendations.<sup>12</sup> The GSV was cannulated



**Fig 2.** Kaplan-Meier (KM) plot of open refluxing great saphenous veins (GSVs). The KM figures represent time to the event. *CI*s, Confidence intervals; *EVLA*, endovenous laser ablation; *RFA*, radiofrequency ablation; *UGFS*, ultrasound-guided foam sclerotherapy.



**Fig 3.** Kaplan-Meier (KM) plot of recurrent varicose veins. The KM figures represent time to the event. *CI*s, Confidence intervals; *EVLA*, endovenous laser ablation; *RFA*, radiofrequency ablation; *UGFS*, ultrasound-guided foam sclerotherapy.

just below the knee, or at the lowest point of reflux on the thigh. The fiber or catheter was advanced to 1 to 2 cm below the saphenofemoral junction and withdrawn during ablation. The EVLA procedure was performed under duplex guidance with a 980-nm diode laser for the first 17 legs, and a 1470-nm for the rest using 12-watt power. Foam was injected through one or two intravenous cannulas in the GSV at knee level and in the thigh. Before injection of the foam, the patient was placed in Trendelenburg position. The progression of foam in the GSV was followed with ultrasound to ensure a complete filling to the junction and subsequent spasm of

the vein. When this was achieved, further injection was stopped. Varicose veins were removed by miniphelectomies during the same procedure in all the treatment groups.

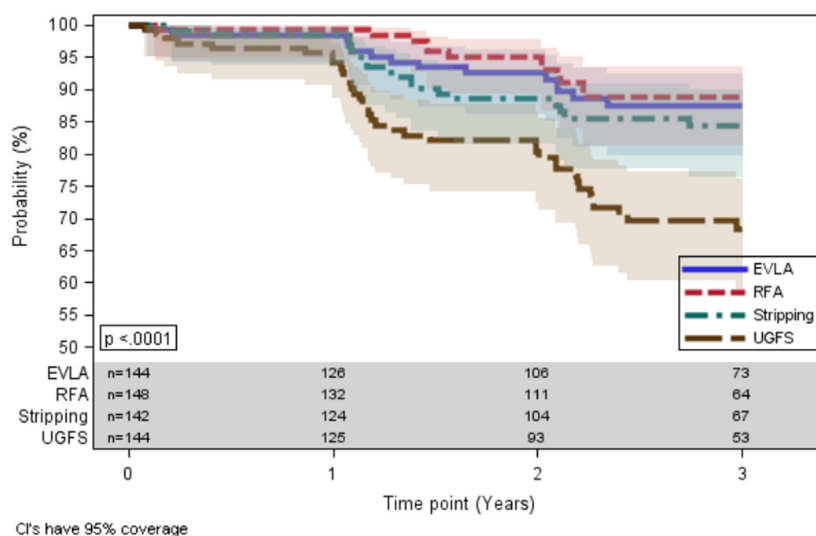
**Assessments.** The patients were examined at the time of randomization, and after 3 days, 1 month, and 1 and 3 years. The present report describes the findings at 1 to 3 years. It is intended to continue the follow-up again at 5 years after the treatment. At the initial visit, the surgeon obtained the medical history, performed a clinical and duplex examination, and determined the CEAP class and VCSS.<sup>13,14</sup> The duration of reflux and the diameter of the

**Table II.** Topographical sites of REVAS: Number of recurrences and pattern of reflux

|                                      | <i>RFA</i> | <i>EVLA</i> | <i>UGFS</i> | <i>Stripping</i> | <i>P</i> |
|--------------------------------------|------------|-------------|-------------|------------------|----------|
| Total legs                           | 148        | 144         | 145         | 143              |          |
| Clinical recurrence                  | 17 (11)    | 24 (17)     | 20 (14)     | 22 (15)          | .66      |
| Reflux in the groin                  | 0 (0)      | 1 (4)       | 4 (20)      | 0 (0)            | .034     |
| Reflux in thigh                      | 10 (59)    | 17 (71)     | 9 (45)      | 14 (64)          | .28      |
| Reflux in popliteal fossa            | 0 (0)      | 1 (4)       | 1 (5)       | 0 (0)            | .57      |
| Reflux in lower leg, ankle, and foot | 12 (71)    | 18 (75)     | 5 (25)      | 13 (59)          | .047     |
| Other                                | 0 (0)      | 0 (0)       | 1 (5)       | 0 (0)            | .39      |

*EVLA*, Endovenous laser ablation; *REVAS*, REcurrence after VARicose vein Surgery; *RFA*, radiofrequency ablation; *UGFS*, ultrasound-guided foam sclerotherapy.

Numbers shown as number of legs (% of recurrences).



**Fig 4.** Kaplan-Meier (KM) plot of reoperations. The KM figures represent time to the event. *CI*s, Confidence intervals; *EVLA*, endovenous laser ablation; *RFA*, radiofrequency ablation; *UGFS*, ultrasound-guided foam sclerotherapy.

GSV 3 cm below the saphenofemoral junction were measured. The Aberdeen Varicose Vein Symptom Severity Score (AVVSS) and the Medical Outcomes Study Short Form 36 (SF-36; Quality Metric, Lincoln, RI) health-related QOL score were completed by the patients and recorded by the research nurse. The AVVSS is a validated instrument for measurement of disease-specific QOL in patients with varicose veins. It produces a score from 0 (no venous symptoms) to 100 (worst venous symptoms).<sup>15</sup> The SF-36 is a generic QOL instrument, which consists of eight domains: physical functioning, role – physical, bodily pain, general health, vitality, social functioning, role – emotional, and mental health. Each domain is scored from 0 (worst) to 100 (best).<sup>16</sup>

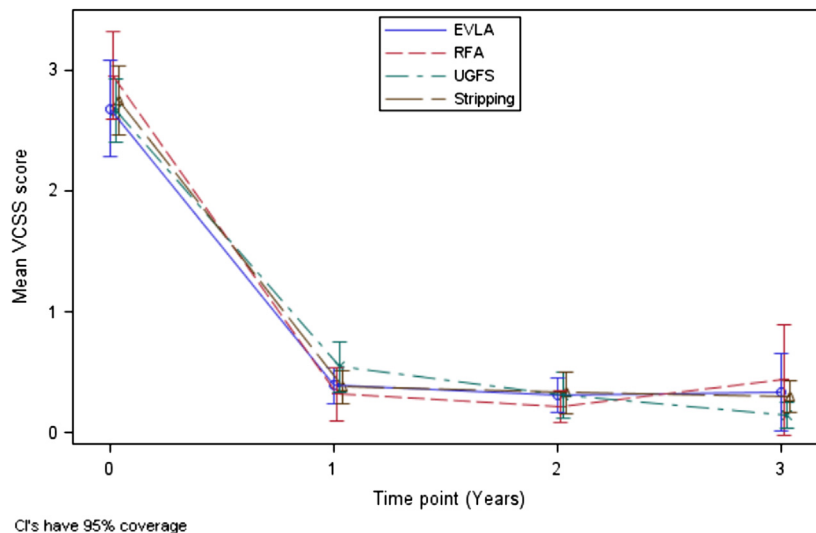
**Statistical analysis.** All analyses were assessed for the full analysis set, comprising all patients undergoing treatment. The primary endpoint, closed or absent GSV, and secondary endpoints, recurrent varicose veins and frequency of reoperations, were analyzed by Kaplan-Meier (KM) survival methods as “time to first” endpoints. The *P* value represents a comparison across all treatment groups

(ie, testing the hypothesis that there are equal treatment effects across all groups). QOL endpoints, AVVSS, SF-36, and VCSS were analyzed using analysis of covariance. The analysis was performed in SAS version 9.1 (SAS Institute, Cary, NC).

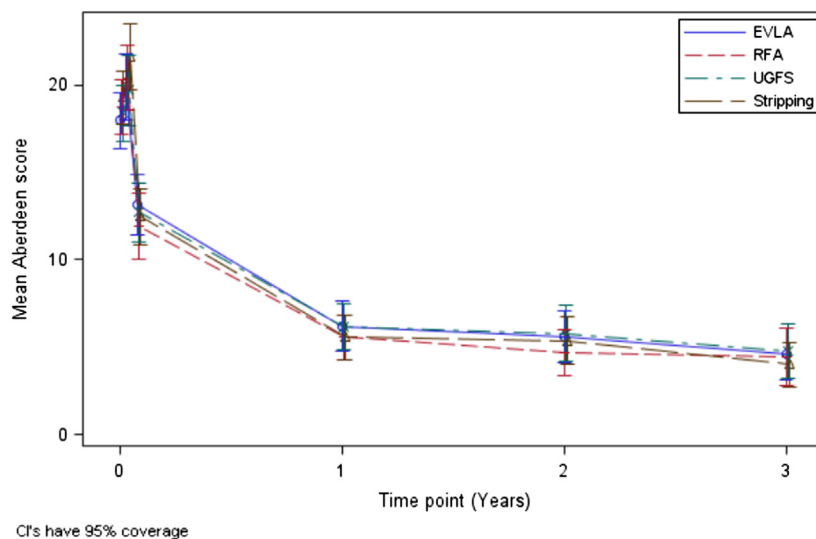
## RESULTS

A total of 500 consecutive patients (580 legs) were randomized to receive treatment. The number of patients and legs treated and examined at follow-up is shown in the CONSORT diagram (Fig 1). Baseline patient characteristics are shown in Table I. The groups were comparable with regard to patient characteristics and CEAP classification of the treated legs. Nine, nine, 10, and 16 patients had undergone previous high ligation and/or phlebectomies in the CLF, EVLA, foam, and stripping group, respectively. Detailed information regarding treatment characteristics has been published before.<sup>11</sup>

**GSV data.** The KM plot of the open, refluxing GSVs are shown in Fig 2. The KM figures represent time to the event, and the probability on the plots is



**Fig 5.** Venous Clinical Severity Score (VCSS). *CI*s, Confidence intervals; *EVLA*, endovenous laser ablation; *RFA*, radiofrequency ablation; *UGFS*, ultrasound-guided foam sclerotherapy.



**Fig 6.** Aberdeen Varicose Vein Severity Score (AVVSS). *CI*s, Confidence intervals; *EVLA*, endovenous laser ablation; *RFA*, radiofrequency ablation; *UGFS*, ultrasound-guided foam sclerotherapy.

freedom from the event. The KM estimates are 1-KM and represent the percentage of patients who had failure, recurrent varicose veins, or reoperation. Eight (KM estimate, 7%), eight (KM estimate, 6.8%), 31 (KM estimate, 26.4%), and eight (KM estimate, 6.5%) of GSVs were recorded as having open and refluxing segments of 10 cm or more during the first 3 years in the CLF, EVLA, UGFS, and stripping group, respectively ( $P < .0001$ ).

**Clinical recurrence and pattern of reflux.** The KM plot of legs with recurrent varicose veins is shown in Fig 3. Recurrent varicose veins were recorded in 17

(KM estimate, 14.9%), 24 (KM estimate, 20%), 20 (KM estimate, 19.1%), and 22 (KM estimate 20.2%) legs during the 3 years in the CLF, EVLA, UGFS, and stripping group, respectively ( $P = .6596$ ). Table II shows the distribution of the recurrent varicose veins. More patients in the UGFS group had reflux in the groin compared with the other groups ( $P = .034$ ).

**Reoperations.** The KM plot of legs with reoperations is shown in Fig 4. Twelve (KM estimate, 11.1%), 14 (KM estimate, 12.5%), 37 (KM estimate, 31.6%), and 18 (KM estimate, 15.5%) legs were retreated in the CLF, EVLA, UGFS, and stripping group, respectively, during the 3-year

**Table III.** SF-36 health-related QOL outcomes after treatment of varicose veins

| SF-36      | Pretreatment  | 1-year        | 2-year        | 3-year        | P <sup>a</sup> to 3 years |
|------------|---------------|---------------|---------------|---------------|---------------------------|
| <b>PF</b>  |               |               |               |               |                           |
| RFA        | 84.05 (18.50) | 92.22 (12.62) | 89.57 (19.83) | 88.03 (17.12) | .0101                     |
| EVLA       | 83.16 (16.85) | 92.02 (11.61) | 88.32 (18.77) | 91.46 (13.82) | <.0001                    |
| UGFS       | 83.49 (17.72) | 91.33 (14.93) | 90.5 (15.7)   | 88.98 (18.21) | .0224                     |
| Stripping  | 83.31 (18.89) | 92.82 (13.35) | 92.69 (12.06) | 90.56 (15.23) | .0008                     |
| <b>RP</b>  |               |               |               |               |                           |
| RFA        | 87.15 (21.44) | 94.65 (10.64) | 92.84 (16.79) | 88.08 (21.47) | .7115                     |
| EVLA       | 83.80 (22.31) | 93.51 (14.78) | 90.21 (19.64) | 90.08 (19.37) | .0054                     |
| UGFS       | 86.49 (21.48) | 90.36 (20.56) | 91.01 (17.73) | 89.7 (20.10)  | .0898                     |
| Stripping  | 85.35 (20.38) | 93.41 (16.32) | 93.75 (16.67) | 90.84 (19.80) | .3390                     |
| <b>BP</b>  |               |               |               |               |                           |
| RFA        | 72.71 (22.37) | 89.92 (16.85) | 87.78 (19.36) | 85.35 (19.93) | <.0001                    |
| EVLA       | 70.94 (20.96) | 88.43 (19.55) | 83.34 (21.21) | 81.22 (26.00) | .0013                     |
| UGFS       | 71.40 (20.37) | 85.11 (23.45) | 83.83 (21.50) | 85.74 (20.61) | <.0001                    |
| Stripping  | 71.30 (22.05) | 88.77 (17.11) | 89.65 (17.73) | 87.86 (19.49) | .0001                     |
| <b>GH</b>  |               |               |               |               |                           |
| RFA        | 62.38 (13.30) | 67.08 (11.82) | 65.33 (12.38) | 62.53 (15.31) | .6055                     |
| EVLA       | 60.55 (13.76) | 64.90 (11.99) | 63.38 (14.14) | 61.11 (15.24) | .5638                     |
| UGFS       | 62.58 (15.00) | 63.36 (18.31) | 62.79 (15.98) | 65.55 (14.77) | .2054                     |
| Stripping  | 63.57 (15.01) | 66.02 (14.00) | 66.58 (12.53) | 65.14 (15.71) | .4618                     |
| <b>VT</b>  |               |               |               |               |                           |
| RFA        | 66.99 (19.30) | 76.00 (17.51) | 79.34 (15.86) | 75.56 (19.26) | <.0008                    |
| EVLA       | 64.68 (18.60) | 77.74 (14.03) | 72.59 (16.65) | 74.60 (17.74) | <.0001                    |
| UGFS       | 68.07 (20.47) | 73.20 (22.67) | 73.46 (17.76) | 74.17 (20.77) | .0910                     |
| Stripping  | 66.90 (21.53) | 76.99 (15.54) | 77.22 (14.88) | 75.32 (18.38) | .0070                     |
| <b>SF</b>  |               |               |               |               |                           |
| RFA        | 93.15 (14.38) | 97.11 (84.45) | 97.56 (11.19) | 93.95 (16.21) | .8255                     |
| EVLA       | 92.93 (15.74) | 96.51 (11.22) | 94.13 (18.03) | 92.86 (16.30) | .8525                     |
| UGFS       | 92.07 (18.41) | 93.10 (16.51) | 95.47 (12.49) | 95.75 (12.72) | .3647                     |
| Stripping  | 90.36 (17.56) | 95.19 (11.60) | 96.52 (10.39) | 96.77 (8.93)  | .0068                     |
| <b>RE</b>  |               |               |               |               |                           |
| RFA        | 91.67 (16.02) | 94.50 (11.02) | 95.58 (12.53) | 92.95 (17.63) | .8807                     |
| EVLA       | 88.67 (20.40) | 95.95 (10.15) | 91.77 (18.93) | 89.42 (21.85) | .5551                     |
| UGFS       | 92.41 (16.73) | 91.92 (17.11) | 92.02 (14.36) | 91.20 (18.42) | .5562                     |
| Stripping  | 88.17 (18.68) | 94.20 (14.02) | 95.52 (12.71) | 94.83 (14.29) | .0243                     |
| <b>MH</b>  |               |               |               |               |                           |
| RFA        | 80.18 (14.70) | 87.08 (11.94) | 86.89 (13.58) | 86.62 (13.89) | .0039                     |
| EVLA       | 80.34 (15.05) | 87.70 (10.51) | 85.90 (13.48) | 83.97 (15.87) | .0914                     |
| UGFS       | 83.00 (16.05) | 84.58 (15.77) | 83.91 (14.03) | 84.34 (16.38) | .8055                     |
| Stripping  | 79.27 (16.04) | 85.92 (12.18) | 87.28 (11.37) | 84.83 (13.21) | .1305                     |
| <b>MCS</b> |               |               |               |               |                           |
| RFA        | 53.97 (8.51)  | 56.52 (6.17)  | 57.26 (6.82)  | 56.34 (7.30)  | <.0001                    |
| EVLA       | 53.72 (8.99)  | 56.74 (5.44)  | 55.92 (6.84)  | 53.90 (10.13) | <.0001                    |
| UGFS       | 55.14 (8.87)  | 54.91 (8.21)  | 54.82 (6.74)  | 55.32 (9.19)  | <.0001                    |
| Stripping  | 53.03 (9.03)  | 55.69 (6.39)  | 56.50 (5.47)  | 55.89 (6.27)  | <.0001                    |
| <b>PCS</b> |               |               |               |               |                           |
| RFA        | 49.11 (8.43)  | 53.24 (5.32)  | 52.09 (7.27)  | 50.66 (7.77)  | <.0001                    |
| EVLA       | 48.27 (7.41)  | 52.62 (5.98)  | 51.12 (7.66)  | 52.33 (6.32)  | <.0001                    |
| UGFS       | 48.25 (8.03)  | 52.14 (7.38)  | 51.76 (7.93)  | 51.89 (8.08)  | <.0001                    |
| Stripping  | 49.20 (7.89)  | 53.51 (5.91)  | 53.11 (5.65)  | 52.27 (7.34)  | <.0001                    |

BP, Bodily pain; EVLA, endovenous laser ablation; GH, general health; MCS, mental component summary; MH, mental health; PCS, physical component summary; PF, physical functioning; QOL, quality of life; RFA, radiofrequency ablation; RE, role—emotional; RP, role—physical; SF, social functioning; UGFS, ultrasound-guided foam sclerotherapy; VT, vitality.

Values are in mean (standard deviation).

<sup>a</sup>P values are adjusted for baseline levels of the respective SF-36 scores.

follow-up ( $P < .0001$ ). Most patients were treated with UGFS, in some cases combined with phlebectomies, which is standard practice in our clinics.

**VCSS.** The VCSS score improved significantly in all groups ( $P < .0001$ ), with no significant difference between the groups at any point in time (Fig 5). The improvement

lasted throughout the 3 years. The mean (standard deviation) VCSS at the start of the study was 2.95 (2.06), 2.68 (2.25), 2.66 (1.45), and 2.75 (1.62) and was reduced to 0.44 (1.82), 0.34 (1.3), 0.15 (0.4), and 0.3 (0.5) at 3 years in the CLF, EVLA, UGFS, and stripping group, respectively.



**AVVSS.** The AVVSS improved significantly in all groups from 3 days and onward ( $P < .0001$ ), with no difference between the groups at any point in time (Fig 6). The mean (standard deviation) AVVSS at the start of the study was 18.74 (8.63), 17.97 (9.00), 18.38 (9.07), and 19.3 (8.46) and was reduced to 4.43 (6.58), 4.61 (5.8), 4.76 (5.71), and 4.00 (4.87) at 3 years in the CLF, EVLA, UGFS, and stripping group, respectively.

**SF-36 scores.** Statistically significant improvements compared with baseline were seen in the domains of physical functioning, role – physical, bodily pain, vitality, social functioning, role – emotional, and mental health at some point in time in some of the groups, and in the mental component summary, and physical component summary at all time points in all groups. (Table III)

## DISCUSSION

Due to recanalization, significantly more patients in the UGFS group developed open refluxing GSV segments of more than 10 cm compared with patients treated with the other modalities. The majority of recanalizations appeared within the first year of follow-up. Our recanalization rate is probably somewhat higher than previously described by authors using sodium tetradecyl sulfate in a similar volume, but it seems to be as good, or even better, than previously described after catheter-directed foam sclerotherapy with Polidocanol.<sup>17-19</sup> Our protocol did not allow retreatment beyond the first month, and only five patients (five legs) received such retreatment.<sup>11</sup> Further sessions of UGFS would undoubtedly have improved the closure rate. The failure to strip the GSV occurred in eight legs because the vein snapped during the procedure and could not be retrieved. Accordingly, this failure represents a technical error, which is well known. No difference in GSV recanalization or failure to strip the vein (failure rate) was found between thermoablation and stripping. Our finding is in line with previous studies comparing EVLA with stripping, showing no difference in efficacy of the two treatments.<sup>20-22</sup> Our study is the first to compare CLF with the other modalities medium term in a randomized trial. It shows that the efficacy of GSV ablation with CLF is not different from EVLA and stripping but considerably better than UGFS. The longer-term clinical impact of recanalized segments of the GSV is not known, however. In the present study with 3-year follow-up, GSV recanalization or failure to strip was not associated with clinical recurrence nor did it seem to influence VCSS or QOL.

The clinical recurrence rate, as defined by the presence of varicose veins after treatment (REVAS), was high in all the groups, with no difference between the groups.<sup>4</sup> Such recurrence is well known from other studies where varicose veins are carefully sought for, and it may well reach more than 60% of legs after 11 years.<sup>5-7</sup> The REVAS classification was not different between the groups, thus a previous finding of increased neovascularization in the groin after stripping compared with EVLA could not be confirmed in the present study.<sup>23</sup> However, such changes were only sought for in legs with REVAS.

More patients in the UGFS group were retreated compared with the other groups because more GSVs recanalized in this group. It is standard practice in our clinics to offer retreatment in patients with a recanalized GSV following a primary treatment. Thus, the retreatment with foam was not necessarily performed because of symptoms or recurrent varicose veins. All four treatments significantly improved VCSS and QOL as reflected by significant improvements in AVVSS and in several domains of SF-36, with no significant differences in the outcome between the groups. The improvements persisted throughout the 3 years and show that CLF, EVLA, UGFS, and stripping are efficient treatments with longer-term beneficial effects in patients with GSV varicose veins. This is true even though more patients in the UGFS group developed recanalization of the GSV. One explanation may be the fact that all treatments were combined with miniphelectomies. Thus, recanalization or failure to strip the GSV does not appear to influence the VCSS and QOL in this study.

A shortcoming of the study is that it was not blinded. Whereas a study comparing different thermoablation modalities may be blinded, it is not possible to blind the treatment for the patient in a study such as ours. Blinding of the observer may be possible, but it is difficult. It should be noted however, that QOL data are based on the patient's own completions of questionnaires. Furthermore, during follow-up visits, the observer would have no access to information of the primary procedure and little recollection of it.

In conclusion, our study demonstrates that CLF, EVLA, UGFS, and stripping are efficient modalities for the treatment of GSV varicose veins in the medium term. Apart from a higher rate of recanalization after UGFS, it appears that there is no difference regarding clinical recurrence, VCSS, and QOL.

## AUTHOR CONTRIBUTIONS

Conception and design: LR, LB, BE

Analysis and interpretation: LR, ML, JS, AB

Data collection: LR, JS, LB, BV

Writing the article: LR, ML, AB

Critical revision of the article: LR, ML, JS, AB, BE, BV

Final approval of the article: LR, ML, LB, JS, AB, BE, BV

Statistical analysis: LR, ML, AB

Obtained funding: LR

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